[DISCUSSION DRAFT]

113TH CONGRESS
2D SESSION

H. R. _____

To require the Secretary of Health and Human Services to provide for recommendations for the development and use of clinical data registries for the improvement of patient care.

IN THE HOUSE OF REPRESENTATIVES

Mr. OLSON introduced the following bill; which was referred to the Committee on _____

A BILL

To require the Secretary of Health and Human Services to provide for recommendations for the development and use of clinical data registries for the improvement of patient care.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. RECOMMENDATIONS FOR DEVELOPMENT AND USE OF CLINICAL DATA REGISTRIES.

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall make recommendations for the

development and use of clinical data registries that are integrated with clinical practice guidelines and best practices or standards of care for the improvement of patient care. The Secretary shall make such recommendations available to the public by posting them on a public Website of the Department of Health and Human Services.

(b) SPECIFIC RECOMMENDATIONS.—Such recommendations, with respect to such registries, shall include the following:

(1) Recommendations for a set of standards that, if adopted, would allow for the bidirectional, interoperable exchange of information between the electronic health records of the reporting clinicians and such registries.

(2) Recommendations on how clinical registries, including outcomes-based registries, may be developed and then used to evaluate various care models and methods, including improved clinical care coordination, and the impact of such models and methods on the management of diseases as measured by appropriate care parameters based on clinical practice guidelines and best practices (such as A1C, blood pressure, and cholesterol levels in the case of diabetes).

(3) Recommendations on how such registries should be structured to facilitate the recording and reporting of post-market data for the purposes of monitoring safety and efficacy of FDA-approved devices and drugs, reporting relevant clinical data to satisfy attestation requirements for coverage of prescribed devices and drugs, and better defining appropriate clinical use in support of evidence development for the Medicare program (such as improving patient access to safe and effective glucose monitoring systems and future glucose monitoring technologies).

(4) Recommendations on how data from such registries may be used to inform physicians and other health care professionals regarding clinical practices for the prevention of diseases (such as diabetes and the precursor conditions of diabetes) and appropriate methods for the dissemination of clinical practice support tools and other educational resources that may be derived from registry data.

(5) Recommendations for how registries can be used to track utilization of preventive health benefits and their impact, such as screenings and the Medicare annual wellness visits that may reduce the risk of chronic diseases, such as obesity, osteoporosis,

cardiovascular disease, cancer, diabetes and their complications.

(c) CONSULTATION WITH CLINICAL EXPERTS.—The Secretary shall consult with national medical specialty societies in the development of such recommendations as they relate to the diseases that they manage and treat (such as with the American Association of Clinical Endocrinologists with respect to recommendations relating to diabetes and pre-diabetes conditions).